UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

VASCULAR SOLUTIONS LLC; TELEFLEX LLC; TELEFLEX LIFE SCIENCES LIMITED; and ARROW INTERNATIONAL LLC,

Plaintiffs,

v.

MEDTRONIC, INC. and MEDTRONIC VASCULAR, INC.,

Defendants.

Case No. 19-CV-1760 (PJS/TNL)

ORDER

J. Derek Vandenburgh, Tara C. Norgard, Joseph W. Winkels, Alexander S. Rinn, Shelleaha L. Jonas, Megan E. Christner, CARLSON, CASPERS, VANDENBURGH & LINDQUIST, P.A., for plaintiffs.

Kurt J. Niederluecke, Lora M. Friedemann, Laura L. Myers, Barbara Marchevsky, and N. Chethana Perera, FREDRIKSON & BYRON, P.A., for defendants.

Plaintiffs Vascular Solutions LLC, Teleflex LLC, Teleflex Life Sciences Limited, and Arrow International LLC (collectively "Teleflex") bring this patent-infringement action against defendants Medtronic, Inc. and Medtronic Vascular, Inc. (collectively "Medtronic"). Teleflex claims that Medtronic's Telescope catheter infringes claims in a family of patents that are directed to guide-extension catheters used in interventional-

cardiology procedures.[1] Medtronic counterclaims for declarations of non-infringement and invalidity.

This matter is before the Court on Teleflex's second motion for a preliminary injunction. For the reasons that follow, the motion is denied.

I. BACKGROUND

Teleflex first moved for a preliminary injunction a few months after filing this action. ECF No. 73. The Court denied the motion, concluding that Medtronic had raised substantial questions concerning the validity of the asserted claims. ECF No. 247; *see Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350–51 (Fed. Cir. 2001) (if the non-movant "raises a substantial question concerning either infringement or validity, *i.e.*, asserts an infringement or invalidity defense that the patentee cannot prove lacks substantial merit, the preliminary injunction should not issue" (citation and quotation marks omitted)). Specifically, the Court found that Medtronic had raised substantial questions concerning whether the asserted claims were either invalid for lack of a written description, *see* 35 U.S.C. § 112(a), or invalid as anticipated by U.S. Patent No. 7,736,355 ("Itou") (or both). With respect to the issue of anticipation, the parties' dispute focused on whether Itou qualified as prior art. After examining the

[1]The technology is described in a *Markman* order entered in another case involving the same family of patents. *See QXMédical, LLC v. Vascular Sols., LLC*, No. 17-CV-1969 (PJS/TNL), 2018 WL 5617568 (D. Minn. Oct. 30, 2018).

record, the Court determined that Medtronic had raised a substantial question concerning that issue and, as noted, denied Teleflex's motion.

In the meantime, Medtronic sought and obtained *inter partes* review ("IPR") before the Patent Trial and Appeal Board ("PTAB") of nearly all of the claims originally asserted in this case. The Court stayed the litigation pending the completion of those proceedings.[2] ECF Nos. 276, 296. The PTAB issued final written decisions on June 7, 2021, ECF No. 301, and the Court's stay expired on July 5, 2021, ECF No. 304.

Among other things, the PTAB found that Itou does not qualify as prior art and consequently does not invalidate any of Teleflex's claims. Keith Decl. [ECF No. 328] Ex. V at 2. At least for the time being, therefore, that invalidity defense is not available to Medtronic in this action.[3] 35 U.S.C. § 315(e)(2). In addition, the PTAB also rejected (albeit without much explanation) the written-description argument on which the Court

[2]Medtronic later sought and obtained IPR review of claims newly asserted in Teleflex's amended and supplemental complaint. *See* ECF No. 301. The PTAB has recently issued final written decisions in this second set of IPRs. *See* ECF Nos. 403, 414–15.

[3]Medtronic has appealed the PTAB's adverse decisions to the United States Court of Appeals for the Federal Circuit. *See* 35 U.S.C. § 319.

relied in denying Teleflex's first motion for a preliminary injunction.[4] Keith Decl. Ex. DD at 62–70.

Armed with these favorable decisions, Teleflex sought and received the Court's permission to bring a second motion for a preliminary injunction. ECF No. 304.

II. ANALYSIS

A. Standard of Review

A court must consider four factors in deciding whether to grant a preliminary injunction: (1) the movant's likelihood of success on the merits; (2) the threat of irreparable harm to the movant if the injunction is not granted; (3) the balance between that harm and the harm that granting the injunction will inflict on the other parties; and (4) the public interest. *Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 114 (8th Cir.

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[4]The adequacy of a written description is not ordinarily a matter for IPR proceedings. *See* 35 U.S.C. § 311(b) (defining scope of IPR). But when a patent owner moves to add substitute claims in place of claims found to be unpatentable—as happened here, Keith Decl. Ex. DD at 3, 56—the PTAB's review of that motion is not bound by the limits of § 311(b). *Uniloc 2017 LLC v. Hulu, LLC*, 966 F.3d 1295, 1304 (Fed. Cir. 2020). Accordingly, in granting Teleflex's motion to add substitute claims, the PTAB addressed and rejected Medtronic's argument that the substitute claims were invalid for lack of written-description support. Keith Decl. Ex. DD at 62–70.

The parties appear to agree that this decision is not binding on this Court, but Teleflex argues that it should be given weight in determining whether Teleflex has shown a likelihood of success on Medtronic's written-description defense. The Court tends to agree, but, as discussed below, the Court finds that Teleflex has failed to establish a likelihood of success on the issue of infringement. The Court therefore need not address any issues of invalidity.

1981) (en banc).[5] Preliminary injunctions are extraordinary remedies, and the party seeking such relief bears the burden of establishing its entitlement to an injunction under the *Dataphase* factors. *Watkins Inc. v. Lewis*, 346 F.3d 841, 844 (8th Cir. 2003).

B. Likelihood of Success

"To establish a likelihood of success on the merits, a patentee must show that it will likely prove infringement of the asserted claims and that its infringement claim will likely withstand the alleged infringer's challenges to patent validity and enforceability." *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1364 (Fed. Cir. 2017). "An accused infringer can defeat a showing of likelihood of success on the merits by demonstrating a substantial question of validity or infringement." *Tinnus Enters., LLC v. Telebrands Corp.*, 846 F.3d 1190, 1202 (Fed. Cir. 2017) (citation and quotations omitted); *see also Amazon.com, Inc.*, 239 F.3d at 1350–51 (if the non-movant "raises a substantial question concerning either infringement or validity, *i.e.*, asserts an infringement or invalidity defense that the patentee cannot prove lacks substantial merit, the preliminary injunction should not issue" (citation and quotations omitted)).

[5]Generally speaking, the Federal Circuit applies regional circuit law when reviewing the grant or denial of a preliminary injunction. *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1363 (Fed. Cir. 2017). But the Federal Circuit gives "dominant effect to Federal Circuit precedent insofar as it reflects considerations specific to patent issues." *Id.* (citation and quotation marks omitted).

As discussed above, Teleflex's first motion for a preliminary injunction turned on Medtronic's invalidity defenses. In this motion, by contrast, the issue of infringement is center stage. For purposes of this motion, Teleflex contends that Medtronic infringes eleven claims spread across five patents:

Patent	*Asserted Claims*
8,048,032	9, 13, 18
RE45,776	25, 36, 37, 52
RE45,380	9, 27
RE47,379	44
8,142,413	4

ECF No. 345 at 11.[6]

Medtronic divides the asserted patents into two groups depending on the location of the claimed side opening: Group One, in which the asserted claims require that the side opening be located *in* the substantially rigid portion[7] (claims 9, 13, and 18 of the '032 patent; claim 4 of the '413 patent; and claim 9 of the '380 patent); and Group

[6]When citing documents by ECF number, the Court cites to the page numbers generated by the Court's electronic docketing system rather than the document's internal pagination.

[7]Some claims use the term "substantially rigid portion" (*see*, *e.g.*, claim 9 of the '032 patent, ECF No. 328-6 at 20), whereas others use the term "substantially rigid segment" (*see*, *e.g.*, claim 25 of the RE'776 patent, ECF No. 328-8 at 22). The parties treat the two terms as interchangeable. For purposes of its discussion, the Court will do likewise.

Two, in which the asserted claims require that the side opening be located *distal* to the substantially rigid portion (claims 25, 36, 37, and 52 of the '776 patent; claim 44 of the '379 patent; and claim 27 of the '380 patent).[8] ECF No. 350 at 21–22. Medtronic argues that the side opening in the Telescope overlaps with, but is not a part of, the substantially rigid portion. As a result, Medtronic contends, the Telescope does not infringe the claims in either group because the side opening is neither in nor distal to the substantially rigid portion.

Medtronic's argument turns on an issue of claim construction—specifically, the construction of "substantially rigid portion." Medtronic contends that "substantially rigid portion" refers to the portion of the device that acts as a pushrod. The "pushrod" is the portion of the device that transmits the force of the user's push to the rest of the device, allowing the rest of the device to advance through the guide catheter. In short, as Medtronic would have it, the substantially rigid portion is the portion of the device that does the pushing rather than the portions of the device (such as the flexible-tip portion) that get pushed.

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[8]Teleflex notes that it disagrees that claim 4 of the '379 patent should be included in Group Two, contending that the prosecution history shows that the side opening may overlap with the substantially rigid portion. For purposes of this motion, however, Teleflex does not dispute Medtronic's grouping of the claims. ECF No. 375 at 10 n.1.

To say that a side opening is "distal" to the substantially rigid portion is to say that it is closer to the heart.

In the Telescope, the pushrod is a long wire that ends proximally in a plastic handle and distally in a spade-shaped radiopaque marker. The distal end is embedded in a polymer that starts as an arc-shaped ramp-like structure and (moving distally) eventually forms a tube. The spade-shaped marker that forms the distal end of the pushrod is embedded distally of the opening of the tube—in other words, distally of the side opening. Zalesky Decl. [ECF No. 366] ¶¶ 49–50, 54, 57–58, 62. As a result, the side opening is seated atop the pushrod and is not distal to it; moreover, there is no opening in the pushrod itself. If Medtronic is correct that "substantially rigid portion" refers only to the pushrod, then the Telescope does not infringe the claims in either Group One (which, on Medtronic's reading, would require the side opening to be in the pushrod) or Group Two (which, on Medtronic's reading, would require the side opening to be distal to the pushrod).

Although Medtronic may not ultimately persuade the Court that its construction of "substantially rigid portion" is correct, Medtronic has raised a strong argument.[9]

[9]The Court notes that, despite having the burden of proving infringement, *Eli Lilly & Co. v. Hospira, Inc.*, 933 F.3d 1320, 1328 (Fed. Cir. 2019), Teleflex did not present any argument concerning infringement in its opening brief (except to argue that Medtronic copied Teleflex's device, which does not by itself establish infringement, *Zenith Laboratories, Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1423 (Fed. Cir. 1994)). Instead, Teleflex simply referred the Court to a portion of its expert's affidavit and attached claim charts, which together comprise nearly 170 pages. *See* ECF No. 345 at 11, 13. This is a transparently improper circumvention of this District's briefing limits. Both parties compounded the problem by together submitting nearly 250 pages' worth

(continued...)

First, as Medtronic points out, this construction is consistent with Teleflex's own history of equating the substantially rigid portion with the pushrod. Zalesky Decl. Ex. 14 ¶ 43 (summary of inventor's opinions in support of Teleflex's claim construction in *QXMédical* stating that "[w]idely available literature from the field of cardiac catheterization uses the term 'substantially rigid' to refer to the push rod of an interventional cardiology device"); *id.* Ex. 33 at 2 (Teleflex's *QXMédical* claim-construction brief referring to "the push rod modifier 'substantially rigid'"); *id.* at 9, 16 (diagrams labeling the pushrod the "substantially rigid portion" and text noting that the substantially rigid portion is "colloquially known as a 'push rod'"); *id.* at 13 (describing the flexible tip, side opening, and "substantially rigid push rod" as the "three key functional components"); *id.* at 17–18 ("Here, the term 'substantially rigid' as used in the relevant claims pertains to the guide extension catheter's push rod" and equating the "rigid portion" discussed in the prosecution history with the pushrod); *id.* at 19 ("The Examiner explained that 'The proximal portion [i.e., the push rod] is disclosed as being substantially rigid."); *id.* at 21 ("As expressly recognized by the Examiner, the term 'substantially rigid' exists to convey on a portion of the device an element of rigidity to permit it to act as a push rod."); *QXMédical*, No. 17-CV-1969, ECF No. 65 at 8 (Teleflex's

[9](...continued)
of slides to the Court in advance of the hearing, only a fraction of which were used during oral argument. The Court warns the parties that it has not, and will not, consider any argument not presented within the parties' briefs.

surreply arguing that its construction of "substantially rigid" "limits flexibility with a necessary degree of rigidity to allow the push rod to perform its function—namely, allowing the application of force to push the device through a guide catheter"); *id.* ECF No. 137 ¶ 95 (Teleflex's expert noting that the "pushrod . . . is the 'substantially rigid' portion referred to by the claims"); Zalesky Decl. Ex. 13 at 61 (Teleflex agreeing at hearing that "substantially rigid" means "rigid enough to allow it to act as a push rod"); *id.* at 63 (Teleflex arguing that the substantially rigid portion is "at least in part designed to . . . act as a push rod" and that "the point behind the push rod is the push"); *id.* at 92–93 ("[W]e embrace the examiner's position that . . . 'substantially rigid' only requires enough rigidity to accomplish what this push rod is there to do."); *id.* at 93 (agreeing with the examiner's interpretation that "substantially rigid" means "flexible with just enough rigidity to have it function as a push rod"); *see also* Zalesky Decl. ¶¶ 83–84 (noting portions of the prosecution history indicating both examiner and inventors treated the substantially rigid portion as the pushrod).

Medtronic's construction is also consistent with the Court's construction of the term "substantially rigid" in *QXMédical*. In that case, the Court adopted Teleflex's proposed construction and gave the term a functional meaning: "rigid enough to allow the device to be advanced within the guide catheter." *QXMédical*, 2018 WL 5617568, at *5. In so doing, the Court followed Teleflex's lead in relying on the fact that "the

function of the substantially rigid portion is to push the tubular structure through the guide catheter and into the coronary artery." *Id.*; *see also id.* ("the intrinsic record in this case leaves little doubt that the main function of the substantially rigid portion is to act as a push rod"); *id.* at *6 (drawing a distinction between "rigid enough *to be pushed*" (referring to the flexible tip portion) and "rigid enough to *do the pushing*" (referring to the substantially rigid portion)); *id.* at *7 ("the main function of the substantially rigid portion is to push the flexible tip portion along the guidewire and into the coronary artery").

Finally, Medtronic's proposed construction makes it simpler for a person of ordinary skill in the art to determine how to map the substantially rigid portion limitation onto an accused device, thereby avoiding a problem introduced by defining a structural limitation in functional terms. In *QXMédical*, QXMédical argued that the Court's functional definition of "substantially rigid" rendered the claims with that limitation invalid as indefinite because, under the Court's construction of that term, a person of ordinary skill in the art would be unable to distinguish the "substantially rigid" portion of the device from the "flexible" portion. *QXMédical, LLC v. Vascular Sols., LLC*, 408 F. Supp. 3d 996, 1003–04 (D. Minn. 2019). The Court recognized that, in the context of the patents-in-suit, "substantially rigid" and "flexible" are not mutually exclusive terms. *Id.* at 1004. Nevertheless, the Court held that its construction of

"substantially rigid" did not render the claims indefinite because a person of ordinary skill in the art "would have no trouble determining whether a pushrod is 'rigid enough to allow the device to be advanced within the guide catheter'" and "whether a substantially rigid pushrod is 'more rigid' than a flexible tip portion." *Id.*

The premise of this ruling is that a skilled artisan would understand the substantially rigid portion to be the pushrod. This is necessary because the artisan must be able to distinguish between the substantially rigid portion and the flexible tip portion *before* measuring and comparing the relative flexibility of the two portions. Otherwise, the artisan would not know which portions of the device to measure and compare.[10]

For all of these reasons, then, Medtronic has made a strong argument that "substantially rigid portion" should be construed to mean only that portion of the device that acts as a pushrod.

In response, Teleflex first argues that Medtronic's construction is incorrect because the specification uses "portion" to refer to longitudinal segments of the device, whether or not those segments are part of a unitary structure or made of multiple components. While that may coincidentally be true for the device described in the

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[10]If this premise is incorrect, the patents may well be invalid for indefiniteness. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014) ("a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention").

patents, it does not necessarily mean that the claims map onto an accused device in the same way; that depends on how the claims are construed.

As discussed above, the Court adopted—at Teleflex's urging—a functional definition of "substantially rigid." It seems anomalous for Teleflex to now advocate construing "substantially rigid portion" in a structural way when the only language in the phrase that distinguishes that portion from the remainder of the device has already been construed in a functional manner. This is particularly true because, as discussed above, this mixture of structural and functional definition could make it exceedingly difficult to distinguish between the substantially rigid portion and other portions of the device. And critically, Teleflex does not point the Court to anything in the claims or specification indicating that "substantially rigid portion" ever refers to anything *other* than the portion of the device that acts as a pushrod.

Teleflex next argues that "portion" is sometimes used to refer to a combination of multiple portions. *See*, *e.g.*, ECF No. 328-6 at 17 col. 6 ll. 38–40 ("Rigid portion 20 includes first full circumference portion 34, hemicylindrical portion 36, arcuate portion 38, and second full circumference portion 40."). This argument does not really address the issue of whether the substantially rigid portion can include components or portions that do not act as a pushrod, however. And again, the fact that the device described in the claims has portions made up of other portions does not necessarily mean that the

claims will map onto an accused device in the same way. In Teleflex's example, for instance, whether the accused device's "rigid portion" also includes the other recited portions depends on the construction of "rigid portion."

Teleflex compares this case to *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336 (Fed. Cir. 2001). But the issue in *Rexnord* was "whether the word 'portion' as used in the claims of the '550 patent should be limited to parts of an object that are 'separate,' as opposed to parts that can be either 'separate' or 'integral.'" *Id.* at 1341. The Federal Circuit held that the district court had erred in concluding that the portions must be separable, holding that "portion" can include both separable parts and parts that are integrated into the whole. *Id.* at 1348. Here, however, the question is not whether different portions of the device may or may not be physically integrated; the question is which portion of the device is the "substantially rigid portion."

Teleflex also similarly argues that a portion may be made of multiple components. But this argument, again, has little to do with whether "substantially rigid portion" must include portions of the device that do *not* provide locomotive force merely because they happen to overlap with portions of the device that do. One could imagine, for example, a pushrod that consists of multiple components that together supply the pushing force that advances the device within the guide catheter; indeed, one could argue that the Telescope's pushrod meets this description, as it is made up of

both a wire and a spade-shaped marker band. The Court does not understand Medtronic to be arguing that the substantially rigid portion cannot consist of multiple components or meet other limitations in the claims (such as featuring a side opening). Instead, Medtronic's argument is that, however many components it consists of and however many other features it has, the substantially rigid portion must transmit the locomotive force that moves the rest of the device through the guide catheter.

Teleflex next argues that the polymer in which the marker band is embedded, and which forms the Telescope's side opening, is rigid. Medtronic offers evidence, however, that the polymer that forms the Telescope's side opening does not *push* but *is pushed*—i.e., the polymer does not act as a pushrod, but instead is pushed along by the pushwire and spade. Zalesky Decl. ¶¶ 128–29. The rigidity of the surrounding polymer is only relevant, therefore, if "substantially rigid portion" means more than just the pushrod. Pointing out that the polymer is rigid does not resolve this issue. It bears emphasis that this Court construed the term "substantially rigid," not the term "substantially rigid portion." The patents are clear that the invention has only a single substantially rigid portion. Thus, it is possible for a part of a device—perhaps a handle attached to a pushrod or a marker band embedded in the flexible tip portion—to *be* substantially rigid and yet not be part of the substantially rigid portion.

Finally, it is worth noting that the manner in which Teleflex maps its asserted claims onto the Telescope arouses the Court's skepticism. For the Group One claims, Teleflex contends that the Telescope's substantially rigid portion extends *beyond* the pushrod and well past the side opening. For the Group Two claims, however, Teleflex contends that the Telescope's substantially rigid portion is *less* than the full pushrod, thereby placing the side opening distal to the substantially rigid portion (as the Group Two claims require). Struggle as it may, the Court cannot find any principled basis for Teleflex's line-drawing.

Teleflex argues that mapping this term in two different ways on the same device is permissible because the two sets of claims are drafted differently. It is true that one set of claims requires the side opening to be in the substantially rigid portion and the other set requires the side opening to be distal to it. But nothing in the claims suggests that the definition of "substantially rigid portion" (or, for that matter, "side opening") changes based on the location of the side opening. As the Court has already discussed, "substantially rigid" has a functional definition—"rigid enough to allow the device to be advanced within the guide catheter." *QXMédical*, 2018 WL 5617568, at *5. That functional definition applies to all claims—both those that require the substantially rigid portion to contain a side opening and those that require the side opening to be distal to the substantially rigid portion.

Teleflex points to *TiVo Inc. v. EchoStar Corp.*, 646 F.3d 869, 883–84 (Fed. Cir. 2011), to argue that different features of a single device can meet the same limitation. This is true, but it is irrelevant to Teleflex's argument. Teleflex is not contending that two different portions of the Telescope meet the substantially rigid limitation. Instead, Teleflex is contending that the *same* substantially rigid portion shrinks or grows as necessary to accommodate two mutually exclusive limitations—namely, the Group One limitation, which requires that the side opening *must* be located in the substantially rigid portion, and the Group Two limitation, which requires that the side opening *must not* be located in the substantially rigid portion. Contrary to the adage that "the map is not the territory," Teleflex here appears to be manipulating the territory to fit the map. And this, in turn, casts yet more doubt—at least in the Court's mind—on Teleflex's entire approach to construing the term "substantially rigid portion." The Court wonders how a skilled artisan could possibly be expected to understand the scope of a patent when the same device could simultaneously infringe two *mutually exclusive* claims within that patent.

In short, the dispute between the parties boils down to an issue of claim construction. Medtronic has offered a strong argument—with which, at this stage of the litigation, the Court is inclined to agree—that "substantially rigid portion" should be construed to mean only that portion of the device that acts as a pushrod. That is the

way that everyone involved in the litigation regarding this family of patents—including the Court, Teleflex, Medtronic, and QXMédical—has been treating the term from the outset. Teleflex's responses appear to be artificial and manipulative, mostly fail to grapple with the claim-construction issue, and completely fail to acknowledge its own history of treating "substantially rigid portion" as synonymous with the pushrod.

For these reasons, the Court finds that Medtronic has raised a substantial question about infringement. As a result, Teleflex's motion for a preliminary injunction must be denied, and the Court need not address any of the other factors. *Nat'l Steel Car, Ltd. v. Canadian Pac. Ry.*, 357 F.3d 1319, 1325 (Fed. Cir. 2004) ("a movant is not entitled to a preliminary injunction if he fails to demonstrate a likelihood of success on the merits").

ORDER

Based on the foregoing, and on all of the files, records, and proceedings herein, IT IS HEREBY ORDERED THAT plaintiffs' motion for a preliminary injunction [ECF No. 325] is DENIED.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: March 21, 2022

Patrick J. Schiltz
United States District Judge